Content on this page was developed during the 2009-2010 H1N1 pandemic and *has not been updated*.

- **The H1N1 virus that caused that pandemic is now a regular human flu virus and continues to circulate seasonally worldwide.**
- **The English language content on this website is being archived for *historic and reference purposes only*.**
- **For current, updated information on seasonal flu, including information about H1N1, see the CDC Seasonal Flu website (http://www.cdc.gov/flu/) .**

General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety

December 15, 2009, 3:15 PM ET

(http://www.myflushot.org) (http://www.cdc.gov/Other/disclaimer.html)

Are the 2009 H1N1 influenza vaccines safe?

The 2009 H1N1 influenza vaccine is showing a similar safety profile to seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects following flu vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are closely monitoring for any signs that the vaccine is causing unexpected adverse events and are working with state and local health officials and other public health partners to investigate any unusual events.

Are there any side effects to the 2009 H1N1 influenza vaccine?

The 2009 H1N1 vaccine is made the same way as seasonal flu vaccines. Millions of seasonal flu vaccines have been given safely. Millions of people have also safely received the 2009 H1N1 vaccine. CDC expects that any side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare. Any side effects that have occurred since people started receiving the 2009 H1N1 vaccine have been similar to those experienced following seasonal influenza vaccine. Mild problems that may be experienced include soreness, redness, or swelling where the shot was given, fainting (mainly adolescents), headache, muscle

aches, fever, and nausea. If these problems occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot is given.

After vaccination you should look for any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, swelling around the eyes or lips, hives, paleness, weakness, a fast heart beat or dizziness. If any unusual condition occurs following vaccination, seek medical attention right away. Tell your doctor what happened, the date and time it happened, and when the vaccination was given. Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report yourself through the VAERS Website (http://www.vaers.hhs.gov/) (http://www.cdc.gov/Other/disclaimer.html) . You may call 1-800-822-7967 to receive a copy of the VAERS form. VAERS is not able to provide medical advice.

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A complete list of possible side effects from both the flu shot and the nasal spray (LAIV or Flu Mist) vaccines are below:

The flu shot: The viruses in the flu shot are killed (inactivated), so you cannot get the flu from a flu shot. Some minor side effects that could occur are:

- Soreness, redness, or swelling where the shot was given
- Fever (low grade)
- Aches
- Nausea

If these problems occur, they begin soon after the shot and usually last 1 to 2 days. Almost all people who receive influenza vaccine have no serious problems from it. However, on rare occasions, flu vaccination can cause serious problems, such as severe allergic reactions. A federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call 1-888-275-4772 or visit the program's website at: "Countermeasures Injury Compensation Program" (http://www.hrsa.gov/countermeasurescomp/default.htm) (http://www.cdc.gov/Other/disclaimer.html) .

The nasal spray (also called LAIV): The viruses in the nasal-spray vaccine are weakened and do not cause severe symptoms often associated with influenza illness. (In clinical studies, transmission of vaccine viruses to close contacts has occurred only rarely.)

In children, side effects from LAIV can include:

- runny nose
- wheezing
- headache
- vomiting
- muscle aches
- fever

In adults, side effects from LAIV can include

- runny nose
- headache
- sore throat
- cough

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Are there some people who should not receive this vaccine?

People who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

How will the 2009 H1N1 influenza vaccines be monitored for safety?

The CDC and FDA closely monitor the safety of seasonal influenza and other vaccines licensed for use in the United States in cooperation with state and local health departments, healthcare providers, and other partners.

The purpose of vaccine safety monitoring is timely identification of clinically significant adverse events following immunization that may be of public health concern. Adverse events, or possible side effects, following immunization may be coincidental to (meaning occurring around the same time but not related to vaccination) or caused by vaccination.

CDC and its partners use multiple systems to monitor the safety of 2009 H1N1 influenza vaccine. Two of the primary systems that are being used to monitor the safety of these vaccines are: the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.

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Vaccine Adverse Event Report System (VAERS)

VAERS (/vaccinesafety/vaers) is a national program managed by both CDC and FDA to monitor the safety of all vaccines licensed in the United States. Anyone can file a VAERS report. VAERS relies on information included in these reports to monitor for clinically serious adverse events or health problems that follow vaccination. Healthcare providers are encouraged to voluntarily report possible adverse events of concern after vaccination, even if they are not certain that the vaccine caused the event. Generally, VAERS cannot determine if an adverse event was caused by a vaccine but can help determine if further investigations are needed. FDA and CDC use VAERS data to help identify potential clinically serious vaccine adverse events or health outcomes. If concerns are identified in VAERS, usually further investigation is needed. One important system used to further evaluate concerns identified in VAERS is the Vaccine Safety Datalink (VSD) (/vaccinesafety/vsd/) Project. More information about VAERS (http://vaers.hhs.gov/) (http://www.cdc.gov/Other/disclaimer.html) is available.

Vaccine Safety Datalink (VSD) Project

The VSD Project (/vaccinesafety/vsd) is a vaccine safety system used to both identify and confirm adverse outcomes after immunization. This project is a collaboration between CDC and eight large managed care organizations, in which comprehensive medical information is collected on approximately 9 million people. The VSD project monitors their data weekly for certain adverse events that could be associated with newly licensed vaccines. VSD conducts studies of vaccine safety adverse events and health outcomes that may arise with any vaccine.

Additionally, CDC works with numerous partners, including other federal agencies, state and local health departments, professional organizations, and academic institutions, to actively follow individuals after vaccination to monitor for any potential adverse events.

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Do the 2009 H1N1 vaccines contain adjuvants?

No. Only unadjuvanted vaccines are being used in the United States during the 2009 flu season. This includes all of the 2009 H1N1 and seasonal influenza vaccines that are available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines contain adjuvants.

2009 H1N1 vaccines with adjuvants are being studied to determine if they are safe and effective. Experts will review these data when they are available. There is no plan at this time to recommend a 2009 H1N1 influenza vaccine with an adjuvant.

Do the 2009 H1N1 influenza vaccines contain thimerosal?

FDA licensed (approved) several formulations ofthe 2009 H1N1 influenza vaccines, including multi-dose vials and single-dose units. Multi-dose vials contain thimerosal as a preservative to prevent potential contamination after the vial is opened.

Some vaccine manufacturers are producing 2009 H1N1 influenza vaccines in single-dose units, which do not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and does not contain thimerosal. More information on thimerosal (/h1n1flu/vaccination/thimerosal_qa.htm) .

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Do the benefits of the 2009 H1N1 influenza vaccines outweigh the risks? Is this something I should talk to my healthcare provider about?

Vaccination is the best way to prevent influenza infection and its complications. This is the reason that CDC, national health organizations, and healthcare providers intensively promote vaccination for seasonal influenza, and the reason why so much work was done to have a vaccine available for the 2009 H1N1 influenza virus.

Seasonal influenza vaccines are highly effective in preventing influenza disease. The vaccines against 2009 H1N1 influenza are expected to work in a similar fashion to the seasonal influenza vaccines. CDC and FDA believe that the benefits of vaccination with the 2009 H1N1 influenza vaccine far outweigh the risks.

Currently the 2009 H1N1 influenza virus (sometimes called “swine flu”) seems to be causing serious health outcomes for:

1. healthy young people from birth through age 24*
2. pregnant women
3. adults 25 to 64 who have underlying medical conditions

* Children, especially those younger than 5 years of age and those who have high risk medical conditions are at increased risk of influenza-related complications. For a more detailed description of children at highest risk, read Children with Developmental Disabilities and Chronic Medical Conditions. (/h1n1flu/childrentreatment.htm) For information about pediatric morbidity, read the Surveillance for Pediatric Deaths Associated with 2009 H1N1 Influenza (/mmwr/) .

Influenza vaccines do not protect against other viruses that cause respiratory illnesses. Even after you are vaccinated, it is still important to wash your hands well and often, to cover your coughs and sneezes, and to stay home if you are sick.

CDC and FDA encourage you to ask your healthcare provider any questions you have about the 2009 H1N1 influenza vaccine and the seasonal influenza vaccines. Your healthcare provider is an excellent

source for information on the benefits and risks of vaccination for protection against 2009 H1N1 influenza for you, your children, and other family members.

CDC is working continuously to provide the public with the most current information about 2009 H1N1 influenza and the 2009 H1N1 influenza vaccine and its safety.

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Is there a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine?

Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Infection with the bacterium Campylobacter jejuni (/ncidod/dbmd/diseaseinfo/campylobacter_g.htm) , which can cause diarrhea, is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. FDA and CDC are closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines, including GBS.

What is the best source of information for 2009 H1N1 influenza vaccine safety?

In addition to talking openly with your healthcare providers, CDC encourages you to stay informed by checking the following web sites often for the most up-to-date news and information: Vaccine Safety (/h1n1flu/vaccination/vaccine_safety.htm) , H1N1 flu (/H1N1flu) , and Flu.gov (http://www.flu.gov/) (http://www.cdc.gov/Other/disclaimer.html) .

Related Links

- Voluntary Non-Safety-Related Recall of Specific Lots of Nasal Spray Vaccine for 2009 H1N1 Influenza - Q & A (/h1n1flu/vaccination/sprayrecall_qa.htm)
- Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes - Q & A (/h1n1flu/vaccination/syringes_qa.htm)

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Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO